Administrative Information for CLIA Categorization

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What is CLIA?

- Clinical Laboratory Improvement Amendments of 1988 (CLIA ‘88)
- Enacted as result of reports of inaccurate test results from Pap smears
- Questions were raised about how laboratories functioned and what quality control procedures existed
- 12,000 out of 200,000 labs were regulated

Who are the Players?

- Health Care Financing Administration (HCFA) was charged to administer the program
- Centers for Disease Control (CDC) was designated to assume responsibilities for complexity categorization aspect of CLIA

What is Categorization?

- Categorization is the process of assigning new commercially marketed laboratory tests/test systems to one of 3 CLIA categories: waived, moderate, high

What is FDA's Role in CLIA?

- Beginning on or about January 31, 2000, the responsibilities for categorization of commercially marketed *in vitro* diagnostic test systems is being transferred from CDC to FDA

What is FDA's Role in CLIA? continued

- The Division for Clinical Laboratory Devices in FDA's Center for Devices and Radiological Health will determine the categorization as they review premarket submissions.

What is FDA's Role in CLIA? continued

- Waived products, devices exempt from premarket notification and test systems under review by the Center for Biologics Evaluation and Research will also be processed

What Regulations Govern Categorization?

- 42 CFR 493.17 implementing CLIA, require that the Secretary provide for the categorization of specific laboratory test systems by level of complexity
- Criteria for such categorizations are set forth in those regulations

Source Documents

- Federal Register (FR) Feb 28, 1992 Vol 57, No. 40--CLIA ‘88 Final Rule
- List of Categorizations: FR 4/11/97, 7/26/93, 9/2/92, 8/28/92, 7/28/92
- Public Health Service Act, Section 353, Oct. 31, 1988
- FDA Modernization Act , Section 123--clarifies that test systems cleared for home use are waived

Sources of Information

- www.fda.gov/cdrh/clia/
- Email account: CLIA@CDRH.FDA.GOV
- CLIA phone number: (301) 827-0496

Requests for Categorization will be:

- Submitted to Document Mail Center
- Tracked in CDRH database
- Subject to internal timelines, to be determined

Standard Operating Procedures are expected to be in place by Dec. 1999 for:

- 510(k) premarket notifications
- 510(k)s exempt by regulation
- Premarket Approval Applications
- Humanitarian Device Exemptions
- Marketing same test under different name (OEM agreement)

It is Expected that Publication of Categorization will be:

- Monthly on FDA's home page
- Federal Register Notice, interval to be determined

What to Expect from the FDA

- Streamlined administrative process
- One stop agency for marketing and categorization